In the United States Court of Federal Claims

ARTHUR L. TROLLINGER,

Petitioner.

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

No. 16-vv-473

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MEMORANDUM AND ORDER

Pending before this Court is Petitioner Arthur L. Trollinger's Motion for Review of the Chief Special Master's Decision (Motion) dismissing Mr. Trollinger's Petition for Vaccine Compensation (Petition) under the National Vaccine Injury Compensation Program (Vaccine Program). Motion for Review of the Chief Special Master's Decision (ECF No. 85) (Mot.); Petition for Vaccine Compensation (ECF No. 1) (Pet.); see Trollinger v. Sec'y of Health & Hum. Servs., No. 16-473V, 2023 WL 2521912 (Fed. Cl. Spec. Mstr. Feb. 17, 2023) (ECF No. 81). Petitioner alleges the Chief Special Master erred by (i) imposing a heightened burden of proof with respect to Althen prong one, (ii) failing to follow the law in his evaluation of Petitioner's expert,

¹ On July 31, 2023, the Court filed a sealed version of this Memorandum and Order. *See* ECF No. 88. As the parties do not propose any redactions, the Court is publicly reissuing its Memorandum and Order. The sealed and public versions of this Memorandum and Order are identical, except for the publication date and this footnote.

and (iii) failing to fairly consider Petitioner's molecular mimicry theory. Mot. at 7–8²; *see Althen* v. *Sec'y of Health & Hum. Servs.*, 418 F.3d 1274 (Fed. Cir. 2005).

Respondent urges this Court to affirm the Chief Special Master's decision, arguing Petitioner has not established reversible error and "has not shown the denial of entitlement was arbitrary, capricious, an abuse of discretion, or not in accordance with law." Response to Motion for Review (ECF No. 87) (Resp.) at 7.

For the reasons stated below, Petitioner's Motion (ECF No. 85) is **DENIED** and the Chief Special Master's Decision is **SUSTAINED**.

BACKGROUND

On April 14, 2016, Arthur L. Trollinger filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986 (Vaccine Act), 42 U.S.C. §§ 300aa-10–34 (2012), for an off-Table injury. Pet. at 1; *Trollinger*, 2023 WL 2521912, at *1. Specifically, Petitioner alleged the Prevnar-13 pneumococcal vaccine (PCV-13) he received on July 17, 2015, caused him to develop Guillain-Barré syndrome (GBS). *Id.*; Pet. PP 2, 14. To support his position, Petitioner provided various medical records³ and expert reports.⁴ Respondent filed competing expert reports⁵

² Citations throughout this Memorandum and Order reference the ECF-assigned page numbers, which do not always correspond to the pagination within the relevant document.

³ Petitioner filed his medical records as Petition Exhibits 1–10 via CD. *See* docket text accompanying Pet. He later filed additional medical records marked as Exhibits 11–12 (ECF No. 9) and Exhibit 13 (ECF No. 11). Petitioner filed a Statement of Completion on June 28, 2016, confirming the submission of all medical records related to this litigation. ECF No. 13.

⁴ Petitioner filed four expert reports throughout this litigation, all from Dr. Lawrence Steinman (ECF Nos. 26-1, 35-1, 67-1, 79-1).

⁵ Respondent filed reports by two experts: Dr. Timothy Vartanian (ECF Nos. 33-1, 38-1) and Dr. J. Lindsay Whitton (ECF No. 77-1).

in support of its opposition and contention that Petitioner's GBS was caused by factors other than the vaccine.

I. Factual Background

On July 17, 2015, Petitioner Arthur L. Trollinger received a PCV-13 vaccine during his annual wellness exam. *Trollinger*, 2023 WL 2521912, at *1; Mot. \$\mathbb{P}\$ 2; Pet. Ex. 1, at 6–7. Eight days later, Petitioner complained of abdominal pains and, concerned he was having a heart attack, contacted emergency medical services (EMS). Pet. \$\mathbb{P}\$ 3; Pet. Ex. 3. EMS arrived over thirty minutes later and offered to take Petitioner to the nearest emergency room. Pet. \$\mathbb{P}\$ 3, at 2; Pet. Ex. 3, at 2. After declining EMS's offer, Petitioner went to the emergency room at the Alamance Regional Medical Center in Burlington, North Carolina (Alamance ER). *Trollinger*, 2023 WL 2521912, at *1; Pet. \$\mathbb{P}\$ 4; Pet. Ex. 3, at 2. There, Petitioner underwent radiological and lab testing, but the treating physician failed to pinpoint a clear cause of the chest pain, ultimately diagnosing Petitioner with gastric reflux. *Trollinger*, 2023 WL 2521912, at *1; Pet. \$\mathbb{P}\$ 4; Pet. Ex. 4, at 441–44, 450–51, 453–84.

Two days later, on July 27, 2015, Petitioner awoke and discovered he had lost feeling in his hands. Pet. ¶ 5. Later that same day, he felt a pins-and-needles sensation and weakness in his legs. *Id.* His wife drove him to a local walk-in clinic, where the physician immediately sent him to the Alamance ER after he developed numbness in his hands and feet, and ptosis (drooping of the upper eyelid) of the right eye. *Trollinger*, 2023 WL 2521912, at *1; Pet. ¶ 5; Pet. Ex. 4, at 40–42, 72–73. The ER physician, Dr. Malinda, conducted a brain scan and consulted with Dr. Matthew Smith, a neurologist, before admitting Petitioner to the hospital for possible GBS.⁶

⁶ While Dr. Vartanian raised concerns about portions of the testing Petitioner had undergone, Respondent does not directly dispute Petitioner's GBS diagnosis, arguing a lack of causation rather than an alternative diagnosis. *See generally* Pet.; Resp.

On August 19, 2015, Petitioner followed-up on his GBS diagnosis with his primary care physician, complaining of difficulty swallowing, chest pains, tachycardia, shortness of breath, back pain, and muscle spasms. *Trollinger*, 2023 WL 2521912, at *2; Pet. Ex. 1, at 4–5. On August 31, 2015, Petitioner met with cardiologist Dr. Dwayne Callwood, who recorded that Petitioner had "developed [GBS] after a pneumonia shot." *Trollinger*, 2023 WL 2521912, at *2; Pet. P 11; Pet. Ex. 9, at 6–13. Dr. Callwood also recorded that Petitioner had suffered from angina symptoms for the previous three to four months, shortness of breath, and tachycardia, and he noted these symptoms were "related to [Petitioner's] [GBS]." *Trollinger*, 2023 WL 2521912, at *2; Pet. P 11; Pet. Ex. 9, at 6.

Petitioner followed up with a neurologist, Dr. Hemang Shah, on September 21, 2015, who documented that Petitioner had received the PCV-13 vaccine in July 2015; however, Dr. Shah did not link the vaccination to Petitioner's symptoms, which were by then improving. *Trollinger*, 2023 WL 2521912, at *2; Pet. Ex. 10, at 9–15; *id.* at 10 (listing PCV-13 as an allergic agent). Dr.

Shah ultimately diagnosed Petitioner with GBS, prescribed Gabapentin, an anticonvulsant and nerve pain medication, and advised Petitioner to avoid driving. *Trollinger*, 2023 WL 2521912, at *2; Pet. Ex. 10, at 15.

When Petitioner underwent further testing on October 2, 2015, he displayed bilateral weakness and numbness in his hands, feet, and legs. *Trollinger*, 2023 WL 2521912, at *2; Pet. P 12; Pet. Ex. 10, at 2–3. Dr. Shah listed that Petitioner's "[p]ast medical history [wa]s significant for pneumonia vaccine prior to gradual onset of symptoms," and provided the impression that Petitioner suffered from "generalized polyneuropathy," with sensory deficits predominant, but "no evidence of conduction block." Pet. Ex. 10, at 2–3 (suggesting that Petitioner's normal median motor response could represent "more proximal lesion"); Pet. P 12; *Trollinger*, 2023 WL 2521912, at *2.

By January 20, 2016, Petitioner's physical condition had improved, but he still required the assistance of a cane to walk. *Id.*; Pet. Ex. 13, at 5. In February 2016, Petitioner's primary care physician referred him to a neurologist. *Trollinger*, 2023 WL 2521912, at *2; Pet. Ex. 13, at 7. Petitioner also had an additional follow-up appointment with his cardiologist, who stated Petitioner's GBS was "possibly related to the pneumonia vaccine." Pet. Ex. 11, at 16; *Trollinger*, 2023 WL 2521912, at *2. On May 31, 2016, Petitioner again visited his primary care physician, who noted Petitioner's GBS symptoms were improving, and that Petitioner was "aware to never get another vaccine." Pet. Ex. 13, at 4–5; *Trollinger*, 2023 WL 2521912, at *2.

At the time Petitioner brought suit against Respondent, Petitioner continued to suffer from numbness and tingling in his hands, wrists, feet, and calves, and experienced tightening in his torso. Pet. ightharpoonup 13.

II. Expert Opinions

In addition to the referenced medical records, the Chief Special Master reviewed seven expert reports filed by three different experts: four reports filed by Petitioner's expert and three reports filed by Respondent's two experts. *See generally* Pet. Ex. 14 (ECF No. 26-1) (Dr. Steinman's First Rep.); Respondent's Ex. A (ECF No. 33-1) (Dr. Vartanian's First Rep.); Pet. Ex. 31 (ECF No. 35-1) (Dr. Steinman's Second Rep.); Respondent's Ex. L (ECF No. 38-1) (Dr. Vartanian's Second Rep.); Pet. Ex. 40 (ECF No. 67-1) (Dr. Steinman's Third Rep.); Respondent's Ex. M (ECF No. 77-1) (Dr. Whitton's Rep.); Pet. Ex. 62 (ECF No. 79-1) (Dr. Steinman's Fourth Rep.).

A. Petitioner's Expert Reports

Petitioner retained Dr. Lawrence Steinman, who serves as the George A. Zimmerman Professor of Pediatrics, Neurology, and Neurological Sciences at Stanford University. Dr. Steinman's First Rep. at 1; *Trollinger*, 2023 WL 2521912, at *3. Dr. Steinman filed four reports in this case. The first report, filed on March 7, 2021, concluded Petitioner had developed GBS through a cross-reactive immune response, molecular mimicry, to the phospholipid molecular structures in the PCV-13 vaccine's antigens. Dr. Steinman's First Rep. at 6–9. Dr. Steinman stated that certain phospholipids (phosphatidyl serine and phosphatidyl choline) are present in the vaccine as well and are expressed in association with its polysaccharide antigens. *Id.* One example is phospholipid phosphorylcholine, which is expressed in the 19A component of the vaccine and is key in the pathophysiology of the pneumonia infection. *Id.* at 8–9. Therefore, in Dr. Steinman's estimation, it was logical that a vaccine intended to immunize against the pneumococcus strain might also bring about "an immune response to lipids involved in neuroinflammation." *Id.* at 9. Dr. Steinman filed his second expert report on August 7, 2017, largely addressing criticisms that

Respondent's expert, Dr. Timothy Vartanian, had leveled at Dr. Steinman's first report. *See generally* Dr. Steinman's Second Rep.

Almost four years later, the Chief Special Master granted Petitioner's request to update Dr. Steinman's expert opinion. Minute Order, dated July 15, 2021. Petitioner's request followed a conversation between Petitioner's counsel and Dr. Steinman, during which the expert "indicated that the current analysis of the molecular mimicry in Prevnar 13 is far more extensive than in his original expert report filed in this case in 2017." July 14, 2021 Status Report (ECF No. 66) at 1. Dr. Steinman's third report was subsequently filed on August 6, 2021. Dr. Steinman's Third Rep. This new report, however, contained no new evidence; instead, Dr. Steinman's third report merely reconsidered existing evidence concerning the makeup and contents of the PCV-13 vaccine. *See id.* After making an inquiry to the Centers for Disease Control and Prevention (CDC) and consulting the vaccine's package insert and patent, Dr. Steinman concluded the molecule at issue in the vaccine was phosphoglycerol, not phospholipids, as Dr. Steinman had previously claimed. *Id.* at 2–15. The information Dr. Steinman had obtained from the CDC was a referral to the vaccine packet and patent, both of which were readily available before Dr. Steinman had filed his first two reports. Dr. Steinman's Third Rep. at 2–6.

With the identification of a new molecule, Dr. Steinman subsequently considered the potential for molecular mimics. *Id.* at 7–15. He focused on phosphoglycerol as a component of some of the vaccine's polysaccharides in the 13 pneumococcal strains included in the vaccine. *Id.* at 6–14. He theorized that an antibody created in reaction to the polysaccharide in the 23F strain could bind to the phosphate group in the phosphoglycerol in the myelin sheath, leading to GBS. *Id.* at 14. In the alternative, he proposed a reaction to a protein conjugate that aids the vaccine's immunogenicity or to the adjuvant used, which stimulates systemic immunity. *Id.* at 15–22.

Petitioner filed Dr. Steinman's fourth report on May 7, 2022. Dr. Steinman's Fourth Rep. at 1. In it, Dr. Steinman introduced several new articles to support his molecular mimicry theory, though they focused on molecular mimics for multiple sclerosis and Epstein-Barr virus rather than GBS. *Id.* at 14–16. Dr. Steinman also defended his research methods in response to criticism from Respondent's expert, Dr. Whitton, and defended the overall value of his evidence. *Id.* at 16–27.

B. Respondent's Expert Reports

Respondent retained two experts who submitted a total of three reports: Dr. Timothy Vartanian, an attending neurologist at New York Presbyterian Hospital and a professor at Weill Cornell Medicine; and Dr. J. Lindsay Whitton, a researcher and professor of immunology and microbial science at Scripps Research Institute, where he focuses on viral pathogenesis, innate and adaptive immune responses, and molecular mimicry. Dr. Vartanian's First Rep. at 1; Respondent's Ex. B. (ECF No. 30-2); Dr. Whitton's Rep. at 1–3; Respondent's Ex. N (ECF No. 77-2).

Petitioner filed expert reports from Dr. Vartanian on May 18, 2017, and on October 27, 2017. Dr. Vartanian's First Rep.; Dr. Vartanian's Second Rep. In these reports, Dr. Vartanian questioned the trustworthiness of Petitioner's GBS diagnosis and highlighted discrepancies between Petitioner's test results and what is expected for persons with demyelinating neuropathy. Dr. Vartanian's First Rep. at 7–10; Dr. Vartanian's Second Rep. at 2–3. He suggested alternative explanations for Petitioner's illness, such as hyponatremia, and stated that one of the drugs taken by Petitioner to treat acid reflux is known to have a negative impact on neuropathies and to exacerbate symptoms for those with hyponatremia. Dr. Vartanian's First Rep. at 7. Dr. Vartanian further contended that Dr. Steinman's molecular mimicry theory was scientifically insufficient. *Id.* at 10–11. Dr. Vartanian's second report served primarily as a response to contentions in Dr.

Steinman's second report, and claimed that Dr. Steinman's theory lacked strong, independent evidence. Dr. Vartanian's Second Rep. at 2–3.

Petitioner filed an expert report from Dr. Whitton on April 29, 2022. Dr. Whitton's Rep. Dr. Whitton's report focused on the causation theories presented by Dr. Steinman, arguing each theory suffered from fatal scientific flaws. *Id*.

III. Special Master's Decision

On January 14, 2022, Petitioner moved for a ruling on the record, asserting his causation-in-fact burden was met. Motion for Ruling on the Record (ECF No. 72). Petitioner relied primarily on Dr. Steinman's causation theory as presented in his expert reports to satisfy the required showing of a reliable, plausible theory of causation. *Id.* at 17 ("Dr. Steinman[] has provided a biologically plausible medical theory that causally connects the Prevnar 13 vaccine with Petitioner's resulting GBS – namely molecular mimicry."). Respondent filed its response to Petitioner's motion on April 29, 2022, arguing Petitioner had failed to establish a reliable medical theory connecting the PCV-13 vaccine and Petitioner's GBS by a preponderance of the evidence. Response to Motion for Ruling on the Record (ECF No. 76) at 1–2.

On February 17, 2023, the Chief Special Master denied Petitioner's motion and entitlement on the basis that the Petitioner "ha[d] not preponderantly established that the pneumococcal vaccine can cause GBS, or did so to [Petitioner]." *Trollinger*, 2023 WL 2521912, at *1. In the Decision, the Chief Special Master analyzed Petitioner's claim using the three-prong causation test for off-Table vaccine injury cases provided in *Althen v. Secretary of Health & Human Services*, which requires a petitioner demonstrate "by preponderant evidence that the vaccination brought about [his] injury." 418 F.3d at 1278. To that end, the *Althen* test's first prong requires Petitioner "provid[e] . . . a medical theory causally connecting the vaccination and the injury." *Id. Althen*

prongs two and three require, respectively, showings of "a logical sequence of cause and effect showing that the vaccination was the reason for the injury" and "a showing of a proximate temporal relationship between vaccination and injury." *Id*.

In applying the *Althen* three-prong test, the Chief Special Master determined Petitioner's proffered causation theory—as evinced by Dr. Steinman—was insufficiently plausible to satisfy *Althen* prong one by preponderant evidence. *Trollinger*, 2023 WL 2521912, at *27–*30. Accordingly, the Chief Special Master ruled Petitioner failed to satisfy *Althen* prong one because Petitioner could not demonstrate by a preponderance of evidence that the pneumococcal vaccine can cause GBS. *Id*.

The Chief Special Master's analysis of the seven expert reports acknowledged that the theory of molecular mimicry is well-accepted in the Vaccine Program as "a reliable scientific explanation for how GBS may often occur after receipt of the flu vaccine specifically." Id. at *27 (emphasis in original). However, the Chief Special Master noted several crucial differences between the flu vaccine and the PCV-13 vaccine that suggest the former's acknowledged relationship to GBS should not be taken as suggestive of the latter's, explaining that "the flu and pneumococcal vaccines are wholly distinguishable in composition, provoke the intended immune response in completely different ways, and evidence relevant to flu vaccine causality is missing for the pneumococcal vaccine." Trollinger, 2023 WL 2521912, at *26. As additional support for his rejection of Petitioner's causation theory, the Chief Special Master also highlighted Dr. Steinman's admittedly incorrect reference to "phospholipids" in his first two expert reports, pointed to perceived weaknesses in Dr. Steinman's research methods and citations, and took account of the arguments and evidence presented in both Dr. Vartanian's and Dr. Whitton's expert reports. Id. at *27–*30.

The Chief Special Master ultimately found that the arguments advanced by Dr. Steinman in favor of Petitioner's causation theory "had a one-size-fits-all quality" that "strained to shoehorn the science behind the flu-GBS association into the context of the pneumococcal vaccine," resulting in errors and leaps of logic that were present even in Dr. Steinman's final expert report. *Id.* at *30. Such perceived deficiencies led the Chief Special Master to hold that Petitioner did not provide a sufficiently persuasive medical theory connecting the PCV-13 vaccine with Petitioner's GBS and thus did not satisfy the first *Althen* prong by a preponderance of the evidence. *Id.* at *30–*31 ("Claimants must carry their burden of proof—here, by preponderantly establishing, via an offering of sufficient evidence specific to the pneumococcal vaccine in question, how it could cause GBS. This has not been accomplished in this case.").

As a petitioner must satisfy all three *Althen* prongs to demonstrate causation, the Chief Special Master found his determination regarding *Althen* prong one was dispositive and accordingly denied entitlement to Petitioner. *Id.*; *Althen*, 418 F.3d at 1274 (requiring a petitioner satisfy all three prongs to demonstrate causation-in-fact).

IV. Petitioner's Motion for Review

On March 17, 2023, Petitioner filed the present Motion for Review (ECF No. 85), urging this Court "to set aside the Decision and enter a ruling in favor of entitlement, or, in the alternative, remand this matter for further consideration as to *Althen* prongs two and three." Mot. at 25. Respondent filed its Response to Motion for Review (ECF No. 87) on April 17, 2023.

APPLICABLE LEGAL STANDARD

The National Childhood Vaccine Injury Act of 1986 (Vaccine Act) created the National Vaccine Injury Compensation Program to compensate people presumed or proven to be injured by certain vaccines. 42 U.S.C. § 300aa-10 *et seq.* Congress established the Vaccine Act after lawsuits

against vaccine manufacturers and healthcare providers threatened to cause vaccine shortages and reduce vaccination rates. *See Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 227–28 (2011). The Vaccine Program was designed to "lessen the number of lawsuits against manufacturers and provide[] relative certainty and generosity of compensation awards in order to satisfy petitioners in a fair, expeditious, and generous manner." *Cloer v. Sec'y of Health & Hum. Servs.*, 654 F.3d 1322, 1325–26 (Fed. Cir. 2011) (internal citations and quotation marks omitted) (alteration in original); *see also K.G. v. Sec'y of Health & Hum. Servs.*, 951 F.3d 1374, 1380 (Fed. Cir. 2020) (citing *Cloer*, 654 F.3d at 1325) ("The Vaccine Act is a pro-claimant regime meant to allow injured individuals a fair and fast path to compensation").

Petitions alleging injuries caused by a vaccine must be filed in the United States Court of Federal Claims, where a Special Master initially reviews and issues a decision on the petition. *Bruesewitz*, 562 U.S. at 228 (citing 42 U.S.C. §§ 300aa-11(a)(1), 300aa-12(d)(3)). Under the Vaccine Act, the United States Court of Federal Claims reviews the Special Master's decision upon the filing of a Motion for Review of Decision of the Special Master. 42 U.S.C. § 300aa-12(e). Upon such a review, the Court may:

- (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
- (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
- (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2); *accord* United States Court of Federal Claims Vaccine Rule 27(c). The standards set forth in 42 U.S.C. § 300aa-12(e)(2)(B), "vary in application as well as degree of deference," as each "standard applies to a different aspect of the judgment." *Munn v. Sec'y of*

Health & Hum. Servs., 970 F.2d 863, 870 n.10 (Fed. Cir. 1992). "Thus, the [United States Court of Federal Claims] judge reviews the special master's decision essentially for legal error or factual arbitrariness." Bradley v. Sec'y of Health & Hum. Servs., 991 F.2d 1570, 1574 (Fed. Cir. 1993).

"[S]pecial masters have broad discretion to weigh evidence and make factual determinations." Dougherty v. Sec'y of Health & Hum. Servs., 141 Fed. Cl. 223, 229 (2018). A special master's factual findings are reviewed under the arbitrary and capricious standard of review. Althen, 418 F.3d at 1278. The scope of this review is limited and highly deferential. Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000). Factual findings of a special master must reflect a consideration of the relevant evidence of record, not be wholly implausible, and articulate a rational basis for the conclusion reached. See, e.g., Cedillo v. Sec'y of Health & Hum. Servs., 617 F.3d 1328, 1338 (Fed. Cir. 2010); Hines ex. rel. Sevier v. Sec'y of Dep't of Health & Hum. Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991). When reviewing the special master's factual findings, this Court does "not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder." *Porter* v. Sec'y of Health & Hum. Servs., 663 F.3d 1242, 1249 (Fed. Cir. 2011). Nor does this Court "second guess the Special Master[']s fact-intensive conclusions[,] particularly in cases in which the medical evidence of causation is in dispute." *Cedillo*, 617 F.3d at 1338 (alteration in original) (quotations omitted) (quoting *Hodges v. Sec'y of Health & Hum. Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993)).

Nonetheless, a deferential standard of review "is not a rubber stamp." *Porter*, 663 F.3d at 1256 (O'Malley, J., concurring in part and dissenting in part). A special master must "consider[] the relevant evidence of record, draw[] plausible inferences and articulate[] a rational basis for

[his] decision." *Hines*, 940 F.2d at 1528; *see* 42 U.S.C. § 300aa-13(b)(1). The special master's findings of fact also must be "supported by substantial evidence." *Doe v. Sec'y of Health & Hum. Servs.*, 601 F.3d 1349, 1355 (Fed. Cir. 2010) (citing *Whitecotton by Whitecotton v. Sec'y of Health & Hum. Servs.*, 81 F.3d 1099, 1105 (Fed. Cir. 1996), *on remand from Shalala v. Whitecotton*, 514 U.S. 268 (1995)). "[A] finder of fact generally is not required to itemize every piece of evidence on an issue and adopt or reject it." *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 540 (2011) (citations omitted). However, the special master cannot dismiss so much evidence that it appears the special master "simply failed to consider genuinely the evidentiary record." *Campbell v. Sec'y of Health & Hum. Servs.*, 97 Fed. Cl. 650, 668 (2011).

DISCUSSION

As an initial matter, this Court acknowledges and greatly empathizes with Petitioner and his struggles with the serious and painful symptoms he has endured. However, after review of the record and applicable law, this Court must deny Petitioner's Motion as a matter of law. Petitioner may disagree with the Chief Special Master's conclusions and believe other special masters would have decided the issue differently. However, the Chief Special Master's factual findings and legal analyses are in accordance with binding precedent and do not reflect arbitrary or capricious reasoning such that reversal and remand by this Court is warranted.

Under the Vaccine Act, Petitioner may demonstrate eligibility for an award in two ways. *See Munn*, 970 F.2d at 865. Petitioner may either (1) show he suffered an injury listed on the Vaccine Injury Table within the requisite time period, in which case causation is presumed (Table injury), or, for injuries not listed on the Vaccine Table, (2) Petitioner may demonstrate his condition was caused-in-fact by a given vaccine (off-Table injury). *Capizzano v. Sec'y of Health*

& Hum. Serv., 440 F.3d 1317, 1319–20 (Fed. Cir. 2006) (citing Munn, 970 F.2d at 865; 42 U.S.C. §§ 300aa-13(a)(1), 300aa-11(c)(1)(C)(ii)(I)). As Petitioner alleges an off-Table injury here, he must prove by a preponderance of the evidence that his vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Shyface v. Sec'y of Health & Hum. Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999); Knudsen v. Sec'y of Dep't of Health & Hum. Servs., 35 F.3d 543, 549 (Fed. Cir. 1994). In showing "that the vaccination brought about [his] injury," Petitioner must satisfy the three Althen prongs, which require Petitioner to show by a preponderance of the evidence:

- (1) a medical theory causally connecting the vaccination and the injury;
- (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and
- (3) a showing of a proximate temporal relationship between vaccination and injury.

 Althen, 418 F.3d at 1278; see also Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1354–55 (Fed. Cir. 2019).

Petitioner advances three arguments against the Chief Special Master's decision and his analysis related to *Althen* prong one: (1) the Decision "imposes a heightened burden of proof with respect to the first *Althen* prong, which is contrary to established Federal Circuit law"; (2) the Decision "fails to follow federal law in evaluating Petitioner's expert, Dr. Lawrence Steinman, which is legal error"; and (3) the Decision "demonstrates a predisposition against Petitioner's molecular mimicry theory, therefore failing to give it fair consideration, which is legal error and . . . arbitrary and capricious." Mot. at 8. The parties agree the relevant facts are not in dispute. *See id.* at 8–9; Resp. at 7 (characterizing the relevant facts as being "not in dispute").

I. Althen Prong One

A. The Chief Special Master Correctly Required Petitioner Satisfy the First *Althen* Prong by a Preponderance of the Evidence.

The first *Althen* prong requires a petitioner to demonstrate that the vaccine at issue is capable of causing the alleged injury. *Althen*, 418 F.3d at 1278; *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355–56 (Fed. Cir. 2006); *Greene v. Sec'y of Health & Hum. Servs.*, 146 Fed. Cl. 655, 663 (2020). To make this showing, "a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be 'legally probable, not medically or scientifically certain." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010) (quoting *Knudsen*, 35 F.3d at 548–49).

Petitioner first argues that the Chief Special Master impermissibly raised the burden of proof for satisfying *Althen* prong one by requiring Petitioner to present a medical theory that satisfies the prong by a preponderance of the evidence. Mot. at 12–13; *see Trollinger*, 2023 WL 2521912, at *27 ("This case turns wholly on the first prong—for I find . . . that Petitioner has not preponderantly demonstrated that the pneumococcal vaccine can cause GBS.") (citation omitted). Petitioner contends such an approach is incorrect because, in his view, a proffered medical or scientific explanation need only illustrate it is biologically plausible that the injury was caused by a given vaccine in order to satisfy the first *Althen* prong. *Id.* at 12–16 ("The Federal Circuit has repeatedly held that biological plausibility (not a preponderance of the evidence) is the appropriate standard for evaluating *Althen* prong one."). Petitioner maintains the preponderance of the evidence standard is applicable only to an analysis of the *Althen* prongs as a whole, "across the entirety of [a] claim," rather than to each prong individually. *Id.* at 13 ("Petitioner does not dispute that he must demonstrate entitlement by a preponderance of the evidence. That burden, however,

is overarching and applies across the entirety of his claim. It should <u>not</u> be applied to the individual *Althen* prongs") (emphasis in original).

Petitioner is mistaken as to the applicable burden of proof for satisfying the first Althen prong, as the Federal Circuit has definitively addressed this topic: "To demonstrate causation, the petitioner's 'burden is to show by preponderant evidence' each of the requirements set forth in Althen" Oliver v. Sec'y of Health & Hum. Servs., 900 F.3d 1357, 1361 (Fed. Cir. 2018) (emphasis added) (quoting Althen, 418 F.3d at 1278); Pafford, 451 F.3d at 1356. Furthermore, the Federal Circuit has made clear that "proof of a 'plausible' or 'possible' causal link between the vaccine and the injury . . . is not the statutory standard" required by the Vaccine Act. Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 (Fed. Cir. 2010); Boatmon, 941 F.3d at 1360 (citing *Moberly*, 592 F.3d at 1322) ("We have consistently . . . reiterated that a 'plausible' or 'possible' causal theory does not satisfy the standard."); Broekelschen, 618 F.3d at 1350 (Fed. Cir. 2010) ("[T]he remaining question is whether [petitioner] provided proof by a preponderance of the evidence of a medical theory "); LaLonde v. Sec'y of Health & Hum. Servs., 746 F.3d 1334, 1339 (Fed. Cir. 2014) (citing *Moberly*, 592 F.3d at 1322) ("[W]e have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden."). Even apart from the Federal Circuit's direction, logic suggests meeting the burden overall by the standard that Plaintiff proposes would require meeting it for each of the individual prongs. Demonstrating by preponderant evidence "a logical sequence of cause and effect" and a "proximate temporal relationship between vaccination and injury" (Althen prongs two and three) but applying a causation theory (Althen prong one) that is not plausible by preponderant evidence would not meet the overall burden of proof requirements, even "across the entirety of [a] claim." Althen, 418 F.3d at 1278; Mot. at 13.

Petitioner cites several Federal Circuit opinions to support his contention that a lower, "biologically plausible" burden of proof is required under the first Althen factor, and more specifically that the burden may purportedly be satisfied by presentation of a medical theory of causation that is considered biologically plausible to any extent. Mot. at 11, 13, 14–16. Petitioner's reliance on these cases is misguided and the cases are inapposite. For example, in Andreu v. Secretary of the Department of Health and Human Services, the Federal Circuit indeed stated a petitioner had satisfied the first Althen prong by presenting a "biologically plausible' theory explaining how toxins in the . . . vaccine could cause seizures," yet the Circuit also made clear the petitioner was required to satisfy that prong by preponderant evidence. 569 F.3d 1367, 1375 (Fed. Cir. 2009); id. at 1379 ("Althen makes clear that a claimant's theory of causation must be supported by a 'reputable medical or scientific explanation.' . . . Medical literature and epidemiological evidence [presented in support of the theory] must be viewed . . . from the vantage point of the Vaccine Act's preponderant evidence standard."). The best reading of Andreu consistent both internally and with Federal Circuit precedent—is thus that the first *Althen* prong is satisfied by a theory demonstrated to be "biologically plausible" by preponderant evidence, not by a lower burden of proof. See id.

Petitioner's citations to *Kottenstette v. Secretary of Health & Human Services*, 861 F. App'x 433 (Fed. Cir. 2021), and *Sharpe v. Secretary of Health & Human Services*, 964 F.3d 1072 (Fed. Cir. 2020), are similarly unpersuasive. In *Kottenstette*, the Federal Circuit confirmed that demonstrating causation under *Althen* does not require "identification and proof of specific biological mechanisms" but "must be supported by a sound and reliable medical or scientific explanation." 861 F. App'x at 440–41 (quoting *Knudsen*, 35 F.3d at 549, and *Simanski v. Sec'y of Health & Hum. Servs.*, 671 F.3d 1368, 1384 (Fed. Cir. 2012)). In *Sharpe*, the Federal Circuit

held a special master had erred in rejecting a petitioner's medical theory "due to an absence of medical literature," quoting *Andreu* for the proposition that "[r]equiring epidemiologic studies . . . or general acceptance in the scientific or medical communities . . . impermissibly raises a claimant's burden under the Vaccine Act." 964 F.3d at 1085 (quoting *Andreu*, 569 F.3d at 1378). However, the holding in *Sharpe* did not suggest anything less than preponderant evidence would meet a petitioner's causation burden. Indeed, contrary to Petitioner's assertions, both opinions expressly confirm preponderance of the evidence is the proper burden of proof under the Vaccine Act. *Kottenstette*, 861 F. App'x at 437 ("*Althen* lists three prongs which petitioners must prove by preponderant evidence."); *Sharpe*, 964 F.3d at 1078 (stating that for off-Table claims, "the petitioner must prove that the vaccine in fact caused her injuries by a preponderance of the evidence. Notably, the preponderance of the evidence standard for off-table claims does not require a petitioner to prove causation with scientific certainty.").

While *Kottenstette*, *Andreu*, and *Sharpe* do not provide a lower burden of proof for satisfying *Althen* prong one, Petitioner correctly relies on them to state that the prong does not require medical certainty or a specific presentation of scientific or medical literature to meet the preponderant evidence burden. *See* Mot. 14–16. However, as Respondent accurately emphasizes, such a rule does not absolve Petitioner from his burden to present a "persuasive" theory supported by "reputable" scientific or medical evidence. Resp. at 10; *Moberly*, 592 F.3d at 1322 ("[A] petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case"). Thus, *Althen* requires a petitioner satisfy prong one by preponderant medical or scientific *evidence*, but a special master cannot require presentation of medical or scientific *literature* to satisfy the prong.

The Decision reflects that the Chief Special Master appropriately followed this approach. The Chief Special Master did not treat the presence or absence of specific kinds of evidence such as medical and scientific literature—in Petitioner's filings as dispositive. Although the Decision highlights how certain evidence previously helped petitioners meet their burdens of proof in other cases, the Chief Special Master did not require Petitioner to provide such evidence to support his causation theory. See, e.g., Trollinger, 2023 WL 2521912, at *28 ("[E]ven in the context of the flu vaccine, . . . cases have often involved successful demonstrations by petitioners that the wild flu viral components of the vaccine contain amino acid sequences that share sequential and structural homology to self-structures (gangliosides) that would be the putative target of autoimmune attack."). Indeed, the Chief Special Master's statement that Dr. Steinman and Petitioner's theory "could pass the preponderant test, if supported by sufficient and reliable medical or scientific evidence" is immediately followed by a reassurance that "[a]ny number of kinds of evidence in combination could meet this standard." Id. (emphasis in original). Such statements do not represent a heightening of the appropriate burden of proof for the first Althen prong, but rather are simple articulations of the appropriate standard for the analysis: a petitioner must provide reliable, preponderant evidence supporting a causation theory to meet the burden of proof but need not provide supportive scientific or medical literature specifically. See Kottenstette, 861 F. App'x at 440–41; *Sharpe*, 964 F.3d at 1078; *Moberly*, 592 F.3d at 1322; *Trollinger*, 2023 WL 2521912, at *28 (discussing Petitioner's need to provide evidence that "crosses the preponderant 'line'").

As the Chief Special Master appropriately required Petitioner demonstrate the plausibility of his causation theory by a preponderance of the evidence, and nowhere required the presentation

of specific types of supporting evidence, Petitioner's argument that the Chief Special Master erroneously applied a heightened burden of proof lacks merit.

B. The Chief Special Master Did Not Use a Credibility Determination to Apply an Erroneous Legal Standard.

Petitioner's second argument contends the Chief Special Master "cloak[ed] the application of an erroneous legal standard in the guise of a credibility determination" concerning Petitioner's expert, Dr. Steinman. Mot. at 16 (quoting Andreu, 569 F.3d at 1379). However, that a special master may "make determinations as to the reliability of the evidence presented to them and . . . as to the credibility of the persons presenting that evidence" is not contested. *Moberly*, 592 F.3d at 1326; Mot. at 18 n.5 ("Of course, Petitioner is not challenging [the Chief Special Master's] credibility evaluation standing alone; rather, it is the use of a credibility determination in combination with an improper evidentiary standard that is problematic."). Petitioner's second argument is thus effectively an extension of his first, contending the Chief Special Master used credibility determinations to apply an improperly heightened burden of proof. Such an argument fails for the same reason articulated above in Discussion Section I.A: the Chief Special Master properly applied the preponderance of the evidence standard to *Althen* prong one. Petitioner does not contend the Chief Special Master's determinations resulted in any burden of proof higher than a preponderant standard, and a review of the Decision does not indicate that the Special Master deviated by applying, for example, either the clear and convincing evidence standard or the beyond a reasonable doubt standard. See Mot. at 14 (claiming the Chief Special Master imposed "a heightened preponderance burden on Petitioner, . . . improperly elevat[ing] the applicable evidentiary standard."). Indeed, the Chief Special Master's Decision frequently references that Petitioner must demonstrate the plausibility of the proffered medical theory by a preponderance of the evidence and reflects that the Chief Special Master analyzed any evidence presented under that standard. *See Trollinger*, 2023 WL 2521912, at *20–*21, *25, *27–*31. Accordingly, Petitioner's second argument similarly lacks merit, as there was not an "erroneous legal standard" applied in the Decision for the Chief Special Master to "cloak . . . in the guise of a credibility determination." *Andreu*, 569 F.3d at 1379; Mot. at 16.

C. The Chief Special Master Afforded Petitioner's Theory Fair Consideration.

Finally, Petitioner contends the Chief Special Master committed legal error by failing to provide Petitioner's medical theory fair consideration due to his purported predisposition against molecular mimicry theories. Mot. at 18–23. As evidence of the Chief Special Master's alleged predisposition, Petitioner cites to other cases in which special masters of this Court accepted molecular mimicry theories—including cases specifically alleging causation between the PCV-13 vaccine and GBS—and criticizes the Decision's comments regarding Dr. Steinman's final expert report. Mot. at 18–23 ("[I]n the case of Prevnar-13 and GBS, three other special masters have considered the precise theory advanced here and all found that *Althen* prong one was satisfied.").

Petitioner's Motion fails to allege a specific legal error brought about by the Chief Special Master's purported predisposition against molecular mimicry. In citing to multiple opinions accepting molecular mimicry theories in various contexts, Petitioner suggests the mere fact that the Chief Special Master rejected the theory is indicative of tainted reasoning. *See* Mot. at 22 ("Appreciating that [the Chief Special Master] may view molecular mimicry with skepticism, it is difficult to understand how four other special masters can accept the precise theory offered by Petitioner here"). Yet, Petitioner concedes other special masters' opinions were not binding on the Chief Special Master, and Petitioner advances no support for the contention that this Court may find a special master to have erred by reaching a different conclusion than some critical mass of their peers. Mot. at 21 ("[T]he decision of one special master is not binding on another special

master in another case."); *see Boatman*, 941 F.3d at 1358–59. Indeed, the Decision contains express acknowledgement of other special masters' opinions and explanations for why the Chief Special Master declined to follow the reasoning of such opinions in this case. *Trollinger*, 2023 WL 2521912, at *26.

Petitioner also highlights the Chief Special Master only cited his own cases in rejecting a molecular mimicry theory for PCV-13 and GBS. Mot. at 20–22 ("[I]t is worth noting that the only cases cited in the Decision that reach a contrary result are decisions written by [the Chief Special Master]."). Again, simply stating that other special masters have found in favor of entitlement when presented with a theory does not equate to the Chief Special Master demonstrating a prejudice against that theory. Nor is the Chief Special Master the only special master to have ruled against entitlement in a case with a GBS diagnosis following a PCV-13 vaccination based on a molecular mimicry theory. See Winkler v. Sec'y of Health & Hum. Servs., No. 18-203V, 2021 WL 6276203 (Fed. Cl. Spec. Mstr. Dec. 10, 2021) (Dorsey, Fed. Cl. Spec. Mstr.), aff'd, 2022 WL 1528779 (Fed. Cl. May 13, 2022), appeal docketed, No. 22-1960 (Fed. Cir. Jun. 28, 2022). Additionally, the Chief Special Master has previously granted entitlement under theories of molecular mimicry in a variety of contexts, suggesting any assumed skepticism towards the theory does not lead to unfair consideration of it. See Lozano v. Sec'y of Health & Hum. Servs., No. 15-369V, 2017 WL 3811124 (Fed. Cl. Spec. Mstr. Aug. 4, 2017), aff'd, 143 Fed. Cl. 763 (2019), aff'd, 958 F.3d 1363 (Fed. Cir. 2020); L.C. v. Sec'y of Health & Hum. Servs., No. 17-722V, 2021 WL 3630315 (Fed. Cl. Spec. Mstr. July 2, 2021); Gerhardt v. Sec'y of Health & Hum. Servs., No. 9-180V, 2014 WL 4712690 (Fed. Cl. Spec. Mstr. Aug. 29, 2014).

Petitioner has thus not provided this Court with indicia of true factual or legal error, but instead appears to be asking this Court to re-weigh the evidence already considered by the Chief

Special Master to reach a pre-determined outcome in line with the other cited special masters. Whether this Court would reach a different conclusion than the Chief Special Master if it conducted a *de novo* review of the facts in the record is of no moment. Such a review would be inconsistent with the appellate posture this Court adopts in vaccine cases, as this Court may not reweigh evidence and instead is limited to determining whether a special master appropriately engaged with the record and provided due consideration such that it cannot be said their conclusions were arbitrary and capricious. *Porter*, 663 F.3d at 1249 (directing that the court does "not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder"); *Lampe*, 219 F.3d at 1363 ("[W]e do not sit to reweigh the evidence. Since the special master's conclusion was based on evidence in the record that was not wholly implausible, we are compelled to uphold that finding as not being arbitrary or capricious."); *Cedillo*, 617 F.3d at 1338 (same).

Upon review of the Decision, this Court does not find the Chief Special Master's conclusions to be arbitrary and capricious. The Chief Special Master clearly conducted a thorough and detailed review of the factual record before him, noting at each step the bases for his determinations. In considering Petitioner's causation theory—featuring molecular mimicry—as presented by Dr. Steinman, the Chief Special Master began by acknowledging the acceptance of molecular mimicry in the context of the flu vaccine and GBS. *Trollinger*, 2023 WL 2521912, at *25–*26. He noted that while other special masters have accepted a similar association between the PCV-13 vaccine and GBS, key differences between the vaccines—their composition, their interactions with the immune system, and the disparate persuasiveness of the evidence in favor of causality—counseled against following suit in this case. *Id.* at *26–*27.

Having illuminated his disagreement with the other special masters and outlined the reasons why he views the flu vaccine-GBS association as lacking persuasive power here, the Chief Special Master proceeded to analyze Dr. Steinman's expert reports and presentations of Petitioner's causation theory. In doing so, the Chief Special Master described the kinds of evidence that have proven persuasive in the flu vaccine-GBS context—including demonstrations that the "wild flu viral components of the vaccine contain amino acid sequences that share sequential and structural homology to self-structures (gangliosides) that would be the putative target of autoimmune attack." *Id.* at *28. The Chief Special Master's analysis of Dr. Steinman's expert reports expresses concern over their paucity of similarly persuasive evidence; however, he does not end his discussion there. Rather, the Chief Special Master detailed his concerns with Petitioner's causation theory, especially in light of the counterarguments expressed by Dr. Vartanian and Dr. Whitton in their expert reports. *Id.* at *28–*29. Specifically, the Chief Special Master noted Dr. Steinman's erroneous reliance on "phospholipids" in his first two expert reports, which, while corrected in later reports, "reasonably call[ed] into question what followed." *Id.* at *28. The Chief Special Master then discussed Dr. Whitton's "numerous insightful critiques of the specific components of the core causation theory," such as a demonstration that "it is not likely that antibodies generated to the phosphoglycerol-specific vaccine antigens can in turn react with host tissue phospholipids, or that GBS is primarily or initially mediated by such a cross-reaction." *Id.* (emphasis omitted). The Decision also expressed concern regarding Dr. Steinman's research methods and reliance on a study that "ultimately stands mostly for the conclusion that the pneumococcal vaccine reliably functions as intended." *Id.* at *29 (emphasis omitted).

The Decision then described with specificity perceived faults in the biological logic of the proffered theory. The Chief Special Master stated Petitioner had not demonstrated by

preponderant evidence that "antibodies produced in response to the pneumococcal vaccine can attack nerve structures and instigate GBS," and that Dr. Whitton "convincingly explained why it could not be assumed, and had not been shown, that an antibody produced in response to one of the vaccine's phosphoglycerol-containing polysaccharides would be recognized by a myelin phospholipid structure." *Id.* Also rejected for lack of credible supporting evidence were Dr. Steinman's arguments concerning cross-reaction between vaccine conjugate and contactin and the "role alum would play in the process of pathogenicity," with the Chief Special Master finding these components of the causation theory to be "bare-bones" and presented "without hardly any evidence" in their favor. *Id.*

Finally, the Chief Special Master discussed the timing of Dr. Steinman's expert reports, using phrasing which Petitioner describes as "[u]nfair and [u]nwarranted." Mot. at 22–23. Petitioner specifically criticizes the Chief Special Master's conclusion "that Dr. Steinman refined his theory *solely* because the case's slow course permitted him the time to do so, rather than because compelling independent reasons existed." *Id.* at 22 (emphasis in original) (quoting *Trollinger*, 2023 WL 2521912, at *30). That statement, however, came at the very end of the Chief Special Master's thorough analysis of the causation theory and Dr. Steinman's reports, voicing a conclusion based on the preceding analysis rather than any animus that clouded it. *See Trollinger*, 2023 WL 2521912, at *30.

Given the breadth and depth of the Chief Special Master's engagement with the record before him, this Court does not find the factual conclusions in the Decision to demonstrate arbitrary and capricious decision making. Petitioner's position that the evidence should have been weighed differently is not sufficient ground to sustain a motion for review, nor is a special master's disagreement with a proffered causation theory proof of a predisposition leading to arbitrary

factual conclusions. That Petitioner does not point to specific evidence allegedly overlooked by the Chief Special Master, does not identify clear errors in the analysis, and does not expressly assert that Petitioner's evidence meets the preponderant standard all suggest Petitioner simply wishes for this Court to reweigh the evidence in the record already afforded consideration by the Chief Special Master. The law requires this Court to decline such an invitation. *See Porter*, 663 F.3d at 1249; *Cedillo*, 617 F.3d at 1338. Accordingly, this Court finds the Chief Special Master to have fairly considered Petitioner's causation theory.

II. Althen Prongs Two and Three

Petitioner urges this Court to "determine that all three *Althen* prongs have been satisfied and therefore issue a decision in favor of entitlement" should this Court determine the Chief Special Master erred in finding Petitioner to fail the first *Althen* prong. Mot. at 24–25. Petitioner cites as the basis for his request Decision footnote 45, which Petitioner characterizes as conceding Petitioner's proffered evidence satisfies both *Althen* prongs two and three. *Id.* (citing *Trollinger*, 2023 WL 2521912, at *27 n.45). Alternatively, Petitioner requests this Court—should it find *Althen* prong one satisfied—"remand this matter for further consideration as to *Althen* prongs two and three." Mot. at 25.

When alleging a vaccine injury not listed in the Vaccine Table, a petitioner must demonstrate causation by satisfying "all three *Althen* prongs by a preponderance of the evidence." *Boatman*, 941 F.3d at 1355; *see Althen*, 418 F.3d at 1278. As discussed, the Chief Special Master did not commit legal error in his analysis related to *Althen* prong one and, accordingly, this Court declines to reverse his conclusion that Petitioner failed to meet the appropriate burden. *See supra* Discussion Sections I.A–C. As Petitioner cannot satisfy *Althen* prong one, Petitioner's request that this Court issue a decision of entitlement, based on a finding that *Althen* prongs two and three

are satisfied, is accordingly denied. Althen 418 F.3d at 1278 (providing a petitioner must satisfy

all three prongs to show "that the vaccination brought about her injury"). This Court denies on the

same grounds Petitioner's request for remand for further consideration as to Althen prongs two

and three.

CONCLUSION

Petitioner's Motion for Review (ECF No. 85) is **DENIED**. The Chief Special Master's

Decision (ECF No. 81) is **SUSTAINED**. The Clerk of Court is **DIRECTED** to enter Judgment

accordingly.

The parties are directed to CONFER and FILE a Notice within 14 days, attaching a

proposed public version of this Memorandum and Order, with any protect information redacted.

IT IS SO ORDERED.

STATE COURT OF ROLES

Eleni M. Roumel

ELENI M. ROUMEL

Judge

July 31, 2023

Washington, D.C.

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